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WILSON SONSINI GOODRICH & ROSATI  
650 PAGE MILL ROAD  
PALO ALTO, CA 943041050

EXAMINER

PRIDDY, MICHAEL B

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/644,026

Applicant(s)

WILLIAMS ET AL.

Examiner

Michael B Priddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 41-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 52 is/are allowed.
- 6) ☐ Claim(s) 41, 43-51, 55-62, 64 and 65 is/are rejected.
- 7) ☐ Claim(s) 42, 54, 63 and 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 44-51, 53, 56-62, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable Büttner-Janz et al. (5,401,269) over in view of Steffee (5,071,437). Büttner-Janz et al. teach an intervertebral disc endoprosthesis comprising a bottom plate 1, a top plate 2, and a prosthesis core 3 having convex superior and inferior surfaces which articulate with concave inner surfaces of the plates 1 and 2. The exterior surfaces of plates 1 and 2 include beveled, projecting teeth 5 for penetrating into the endplates of the vertebrae. These teeth 5 project from the surface of the plates angularly. Therefor, Büttner-Janz et al. teach all of the limitations of the present invention except that the teeth 5 comprise lumens extending therewithin. Concerning the limitations of claim 50, requiring the intradiscal component be coupled to either the first or second anchor plates, the examiner directs applicants attention to Figs. 8 and 9 in which core 3 includes a rib 11 and each of the plates 1 and 2 include grooves for receipt of the rib 11. This couples the core 3 to each of the plates 1 and 2.

Steffee teaches an artificial disc 5 which comprises an upper flat plate 12, a lower flat plate 14 and an elastomeric core 16 between the two rigid plates. Each of the flat plates is covered with a porous coating 26 and from each of the flat plates extend a

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plurality of anchoring elements 28 capable of being introduced into the vertebra. The anchoring elements each include lumens 29 therethrough which allow communication of the interior thereof with the exterior. It would have been obvious to one of ordinary skill in the art at the time of the present invention to have provided lumens within the teeth the prosthesis of Büttner-Janz et al. so as to allow for communication of the interior of the teeth with the exterior thereby improving biocompatibility and/or ingrowth characteristics.

Concerning the language requiring the anchoring elements have outer walls that extend substantially perpendicular from the plate member, Applicant has not convincingly demonstrated that this particular shape for the anchoring elements is critical. The specification does mention that the anchoring elements should be of a shape which will "minimize the risk of splintering the vertebra by introducing the anchoring elements into the vertebra" but also indicates that the anchoring elements can extend from the plate member substantially vertically, *angularly or curved*". Furthermore, the specification indicates that the "anchoring elements can have a plurality of shapes including cone, cylinder, triangle, square, rectangle and other irregular shapes". It is therefore the examiner's conclusion that it would have been an obvious matter of design to one of ordinary skill in the art at the time of the present invention to have formed the lumens of any shape desired.

Claims 43 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Büttner-Janz et al. in view of Steffee as applied to claims 41 and 53 above, and further in view of reasoning which follows. Büttner-Janz et al. and Steffee teach all of

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the limitations of the present invention except that the lumens within the teeth or anchoring elements are .5 mm in diameter. Applicant has not convincingly demonstrated the criticality of this particular dimension and it would therefore have been an obvious matter of design to one of ordinary skill in the art at the time of the present invention to have formed the lumens of whatever diameter was appropriate to the dimensions of the device as whole.

### ***Response to Arguments***

Applicant's arguments concerning the shape of the anchoring elements of the present invention are believed substantially addressed by the new language of the rejection under 35 U.S.C. 103(a) above.

### ***Allowable Subject Matter***

Claims 42, 54, 63 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

2. Claim 52 is allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Thurs. from 7:30 a.m. to 4:30 p.m.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy

*Michael B. Priddy*  
02/23/2003

*Kevin Shaver*  
KEVIN SHAVER 2/24/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700